

(51) International Patent Classification ⁵ : A61N 5/02	A1	(11) International Publication Number: WO 92/18199 (43) International Publication Date: 29 October 1992 (29.10.92)
(21) International Application Number: PCT/US91/02509 (22) International Filing Date: 12 April 1991 (12.04.91) (71) Applicant: MMTC, INC. [US/US]; 12 Roszel Road, Suite A-203, Princeton, NJ 08540 (US). (72) Inventor: STERZER, Fred ; 4432 Province Line Road, Princeton, NJ 08540 (US). (74) Agent: SELIGSOHN, George, J.; MMTC, Inc., 12 Roszel Road, Suite A-203, Princeton, NJ 08540 (US). (81) Designated States: AT (European patent), BE (European patent), CA, CH (European patent), DE (European patent), DK (European patent), ES (European patent), FR (European patent), GB (European patent), GR (European patent), IT (European patent), JP, LU (European patent), NL (European patent), SE (European patent).		Published <i>With international search report.</i>

Applying squeezing pressure to a diseased prostate, by means of a urethral and/or rectal catheter (100) incorporating an inflatable prostate balloon (122); to compress the prostate while it is being irradiated from a microwave antenna (116), increases the therapeutic temperature to which the prostate tissue more distal to the microwave antenna (116) can be heated without heating any non-prostate tissue beyond a maximum safe temperature, and reduces the temperature differential between the heated more distal and more proximate prostate tissue from the microwave antenna (116).

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	ES	Spain	MG	Madagascar
AU	Australia	FI	Finland	ML	Mali
BB	Barbados	FR	France	MN	Mongolia
BE	Belgium	GA	Gabon	MR	Mauritania
BF	Burkina Faso	GB	United Kingdom	MW	Malawi
BG	Bulgaria	GN	Guinea	NL	Netherlands
BJ	Benin	GR	Greece	NO	Norway
BR	Brazil	HU	Hungary	PL	Poland
CA	Canada	IT	Italy	RO	Romania
CF	Central African Republic	JP	Japan	RU	Russian Federation
CG	Congo	KP	Democratic People's Republic of Korea	SD	Sudan
CH	Switzerland	KR	Republic of Korea	SE	Sweden
CI	Côte d'Ivoire	LI	Liechtenstein	SN	Senegal
CM	Cameroon	LK	Sri Lanka	SU	Soviet Union
CS	Czechoslovakia	LU	Luxembourg	TD	Chad
DE	Germany	MC	Monaco	TG	Togo
DK	Denmark			US	United States of America

5

10 CATHETERS FOR TREATING PROSTATE DISEASE

Background of the Invention

This invention relates to the use of microwaves for the treatment of prostate disease and, more particularly, to catheters designed to efficiently irradiate the prostate of a male patient with microwave power.

As known in the art, prostate disease, such as prostate cancer or benign prostatic hypertrophy (BPH), inter alia, results in a narrowing of the urethra in the neighborhood of the prostate caused by the surrounding enlarged prostate. This narrowing restricts the passage of urine. As is also known, a diseased prostate can be treated by irradiating prostate tissue with an amount of microwave power sufficient to heat that prostate tissue to a therapeutic temperature. However, the maximum microwave power that can be used is limited by the fact that it is essential that none of the prostate tissue be overheated beyond a maximum therapeutic temperature and that none of the irradiated non-prostate tissue be heated beyond a maximum safe temperature (which maximum safe temperature for non-prostate tissue is below the maximum therapeutic temperature for prostate tissue).

Catheters designed to be inserted into the urethra that help pass urine and bulb applicators designed to be inserted into the rectum of the patient, which have been fitted with a microwave antenna, have been used in the past to irradiate the prostate tissue of the patient with microwave power. A urethral catheter is often equipped with a so-called Foley balloon located close to the tip thereof, which may be inflated (usually with air) after the tip of the urethral catheter has been inserted

into the patient's bladder, thereby to secure the catheter at its fully inserted position within the patient's urethra. A bulb applicator may be made non-symmetrical so that, after full insertion into a patient's rectum, the microwave power preferen-

5 tially irradiates the patient's prostate tissue.

Regardless of whether the patient's prostate tissue is irradiated with microwave power radiated by the microwave antenna from the patient's urethra or rectum, it is apparent that non-prostrate tissue situated between the patient's prostate and

10 urethra or rectum, as the case may be, also will be irradiated. Further, since the microwave field intensity tends to vary as an inverse function (e.g., as an inverse square) of distance from the microwave antenna, this non-prostate tissue will be more highly irradiated than will the prostate tissue (particularly

15 that prostate tissue situated more distal to the microwave antenna), because the irradiated non-prostate tissue is more proximate to the microwave antenna. Therefore, the difference between the respective microwave-field intensities heating the more proximate irradiated non-prostate tissue and the more distal

20 irradiated prostate tissue varies as an inverse function of the ratio of their respective distances from the microwave antenna. Thus, in order to heat the more distal prostate tissue to a higher therapeutic temperature without concurrently either overheating any of the more proximate prostate tissue or heating

25 the more proximate non-prostate tissue beyond a maximum safe temperature, it would be desirable to increase the minimum distance between the microwave antenna and the more proximate non-prostate tissue, without appreciably affecting the distance between the more distal prostate tissue.

30

Summary of the Invention

The present invention contemplates increasing the minimum distance between the microwave antenna and the more proximate non-prostate tissue by applying squeezing pressure to

35 such more proximate tissue.

More specifically, the present invention is directed to an improved catheter adapted to be inserted into an orifice of a male patient for treating prostate disease, wherein the catheter comprises means including microwave antenna means for irradiating the patient's prostate with a given distribution of microwave field intensity, thereby to heat tissue of the patient to a temperature which tends to vary as a direct function of microwave power and as an inverse function of the distance of that tissue to the microwave antenna means, and wherein the maximum microwave power to be employed is limited to an amount at which the temperature of the patient's heated tissue most proximate to the microwave antenna means does not exceed a given safe maximum temperature.

The improvement comprises an inflatable balloon (1) which is adapted to be in a deflated state while the catheter is being inserted into the orifice, (2) which is located in the catheter at a position which is in cooperative relationship with the patient's prostate when the catheter is fully inserted, and (3) which is adapted to be inflated when the catheter is fully inserted for applying squeezing pressure to both prostate tissue and that non-prostate tissue situated between the inflated balloon and the prostate tissue, thereby increasing the minimum distance between heated tissue of the patient and the microwave antenna means. The desirable result is that the maximum microwave power may be increased without exceeding the given maximum safe temperature and the temperature differential between the heated prostate tissue more proximate to the microwave antenna means and the heated prostate tissue more distal to the one microwave antenna means is reduced.

30

Brief Description of the Drawings

Figures 1, 1a and 1b, taken together, diagrammatically illustrate a urethral catheter for treating prostate disease, which urethral catheter incorporates a first embodiment of the present invention;

35

Figure 1c diagrammatically illustrates a modification of the aforesaid urethral catheter;

Figures 2a and 2b, taken together, illustrate the advantages of the aforesaid urethral catheter;

5 Figure 3 diagrammatically illustrates a rectal catheter for treating prostate disease, which rectal catheter incorporates a second embodiment of the present invention, and also illustrates the advantages of this rectal catheter;

10 Figures 3a and 3b, taken together, illustrate a first modification of the rectal catheter illustrated in Figure 3; and

Figures 3c and 3d, taken together, illustrate a second modification of the rectal catheter illustrated in Figure 3.

Preferred Embodiments of the Invention

15 Like urethral catheters of the prior art, the urethral catheter shown in Figures 1, 1a and 1b comprises a member defining longitudinal catheter bore 100 and an inflatable Foley balloon 102 surrounding bore 100. A tip portion 104, located in front of Foley balloon 102, terminates bore 100 in a smooth tip

20 106. Tip portion 104 together with Foley balloon 102 in a deflated state are intended to be inserted into the bladder of a patient and then, by inflation of Foley balloon 102, catheter bore 100 is maintained in substantially fixed position within the urethra of the patient. As indicated in Figure 1a, tip 106

25 includes several perforations 108 which permit urine to be channeled from the patient's bladder to urine lumen 110 of bore 100, through which the patient discharges urine. In order to inflate Foley balloon 102, lumen 112 (Figure 1b) extends from Foley balloon 102 to Foley balloon inflation valve 114 attached

30 to the rear of bore 100. Treatment of prostate disease with microwaves requires that the urethral catheter includes a properly located microwave antenna 116, which is connected to an external microwave power source over transmission line 118 (Figure 1) that runs through microwave lumen 120 (Figure 1b).

35 Further, as known but omitted from the drawing, treatment of

prostate disease with microwaves requires the use of a thermometer (preferably digital), including one or more suitably placed temperature sensing probes, for ascertaining the temperature of tissue heated by the microwaves.

5 In accordance with the principles of the present invention, the urethral catheter shown in Figures 1, 1a and 1b also includes prostate balloon 122 surrounding bore 100 and longitudinally located behind Foley balloon 102 and in cooperative relationship with microwave antenna 116. More specifically,
10 microwave antenna 116 and prostate balloon 122 are longitudinally situated at a distance from tip 106 such that when bore 100 is fully inserted in the urethra of a patient, elements 116 and 122 are in cooperative alignment with the patient's prostate. In order to inflate prostate balloon 122, prostate balloon lumen 124
15 (Figure 1b) extends from prostate balloon 122 to one or more prostate balloon inflation valves 126 attached to the rear of bore 100. Preferably, microwave antenna 116 and microwave lumen 120 are axially situated with respect to the axis of bore 100 (in which case the other lumens 110, 112 and 124 are situated off-
20 axis, as shown in Figure 1b), so that the distribution of the microwave field intensity irradiating the patient's prostate is angularly non-directional.

 The size of catheters is conventionally measured in French units. A typical size for the urethral catheter shown in
25 Figure 1 is 16 French. Typically, the length of the bore 100 between its tip and its attachment to valves 114 and 126 is about 360 millimeters (mm); the length of tip portion 104 is about 25 mm; the length of Foley balloon 102 is about 10 mm; the distance between Foley balloon 102 and prostate balloon 122 is about 4 mm;
30 and the length of prostate balloon 122 is about 40 mm. Further, the minimum diameter of microwave lumen 120 is about 2.5 mm.

 In practice, while the catheter shown in Figures 1, 1a and 1b is being inserted into the urethra of a patient with prostate disease, both the Foley and prostate balloons are in a
35 deflated state. This both makes for easier insertion and

minimizes pain to the patient. After full insertion (i.e., the deflated Foley balloon reaching into the patient's bladder), a fluid (usually air) is pumped through the Foley inflation valve thereby to inflate the Foley balloon and hold the catheter within the patient's urethra. However, the catheter is still capable of limited longitudinal movement with respect to the urethra. After the Foley balloon has been inflated, a fluid, preferably a low-loss radio-opaque liquid (e.g., deionized water in which a small amount of a radio-opaque substance has been dissolved), is slowly pumped through the one or more prostate inflation valves into the prostate balloon. The use of a radio-opaque liquid permits fluoroscopy of inflated prostate balloon 206-b to be employed to first align the longitudinal position of the prostate balloon with the patient's prostate and then insure that the prostate balloon is inflated by the proper amount to apply a squeezing pressure that results in a desired compression of the prostate tissue.

It is desired to heat the diseased prostate tissue to a therapeutic temperature without heating the non-prostate tissue lining the urethra, which intervenes between the microwave antenna and this prostate tissue, beyond a maximum safe temperature. However, the irradiating microwave field intensity, which varies as an inverse function (e.g., inverse square) of the distance between the microwave antenna and the heated tissue, is higher for the intervening non-prostate tissue than it is for the prostate tissue and is higher for the more proximate prostate tissue than it is for the more distal prostate tissue. The use of an inflated prostate balloon, employed by the present invention, mitigates this problem, as shown in Figures 2a and 2b.

Figures 2a and 2b show that the radial distances of the urethral catheter from microwave antenna 200 to prostate tissue 202 and intervening non-prostate tissue 204 with a deflated prostate balloon 206-a and with an inflated prostate balloon 206-b, respectively. As shown, inflated prostate balloon 206-b forms a circumferentially symmetrical toroid extending around the

entire circumference of the urethral catheter. Specifically, the radial distance R_{1b} from microwave antenna 200 to the beginning of non-prostate tissue 204 with inflated prostate balloon 206-b is significantly larger than the corresponding radial distance R_{1a} with deflated prostate balloon 206-a. Similarly, the inner radius R_{2b} of prostate tissue 202 with inflated prostate balloon 206-b is significantly larger than the corresponding radial distance R_{2a} with deflated prostatic balloon 206-a. However, of particular significance is that, because prostate tissue is soft and compressible, the difference between the outer and inner radii R_{3b} and R_{2b} of prostate tissue 202 with inflated prostate balloon 206-b is substantially reduced with respect to the corresponding difference between radii R_{3a} and R_{2a} with deflated prostate balloon 206-a. Thus, both the variation in the respective microwave field intensities heating any part of the intervening non-prostate tissue and heating any part of the diseased prostate tissue and the variation in the respective microwave field intensities heating the more proximate and more distal prostate tissue are significantly reduced by the use of an inflated prostate balloon. This makes it possible to heat the prostate tissue more evenly and to higher therapeutic temperatures without heating any part of the non-prostate tissue beyond its maximum safe temperature.

Obviously, increasing the microwave power radiated from the microwave antenna will tend to increase the respective temperatures reached by both the prostate tissue and the intervening non-prostate tissue. The modification of the urethral catheter shown in Figure 1c makes it possible to increase the microwave power, to thereby increase the therapeutic temperatures reached by the more distal parts of the diseased prostate tissue without overheating the more proximate parts of the prostate tissue or any part of the intervening non-prostate tissue lining the urethra. The modification comprises replacing single prostate balloon lumen 124 of Figure 1b with both prostate balloon inlet lumen 128 and prostate balloon outlet lumen 130 of

Figure 1c. This permits the pumped fluid (e.g., radio-opaque liquid) inflating prostate balloon 122 to be circulated there-through and act as a coolant for removing heat preferentially from the non-prostate tissue adjacent thereto. Either or both of
5 inlet and outlet lumens 128 and 130 may be associated with a prostate balloon inflation valve 126, shown in Figure 1, which may be operated by a thermostat that controls the circulation of the coolant in a manner to maintain the non-prostate tissue at a temperature near, but never exceeding, its maximum safe tempera-
10 ture.

As is known, prostate disease is often treated with microwaves applied to the prostate tissue from the patient's rectum by means of a bulb applicator. A diseased prostate, which is enlarged, tends to form a bulge which protrudes into the
15 patient's rectum. A problem with such a bulb applicator is that its insertion into the rectum tends to push aside the protruding bulge, which is quite painful to the patient. The rectal catheter shown in Figure 3, which forms a second embodiment of the present invention, overcomes this problem. In addition, the
20 rectal catheter shown in Figure 3 also possesses the advantages of the urethral catheter, discussed above. More particularly, while the structure of the rectal catheter is generally similar to that of the urethral catheter discussed above (either with or without the modification shown in Figure 1c), it differs
25 therefrom in several ways. First, the rectal catheter has a larger diameter bore 300 in order to properly fit the rectum. Second, because an inflated balloon is elastic, prostate balloon 302, when inflated, forms a bowl 304 that stretches to substantially conform to the bulge of the enlarged prostate protruding
30 into the patient's rectum (rather than being circumferentially symmetrical like the urethral catheter discussed above). Third, because the prostate is located only on one side of the rectum, microwave antenna 306 (energized through transmission line 318) is situated off axis, closer to the prostate, so that the
35 prostate tissue and the intervening non-prostate tissue between

the prostate and rectum is preferentially irradiated with respect to the irradiation of the remaining non-prostate tissue surrounding the rectum. A more complex antenna means incorporating a directional microwave antenna (which may be comprised of a reflector, director and/or phased array) may be utilized to further preferentially irradiate the prostate tissue. Further, such a directional antenna need not necessarily be situated off axis in order to preferentially irradiate the prostate tissue.

Figures 3a and 3b, taken together, show an example of a rectal catheter employing a directional microwave antenna comprised of reflector 320 partially surrounding centrally located microwave antenna 306 and positioned to preferentially irradiate the prostate tissue.

Figures 3c and 3d, taken together, show an example of a rectal catheter employing a directional microwave antenna comprised of a phased array made up of a power splitter 322, four phase shifters 324 and four antenna elements 326. Power splitter 322 distributes the microwave power applied through transmission line 318 to each of the four antenna elements 326 through one of the four phase shifters 324. Each of the four phase shifters is appropriately adjusted to cause the four antenna elements 326 to emit a shaped radiation pattern 328 that preferentially irradiates the prostate tissue.

In practice, the rectal catheter is inserted into the rectum of the patient with its prostate balloon 302 in a deflated state. This substantially eliminates the pain that the patient felt when a bulb applicator was inserted. Before inflating prostate balloon 302, it is oriented in substantial cooperative relationship with the bulge of prostate tissue and intervening non-prostate tissue. Therefore, slow inflation of prostate balloon 302 results in the creation of a bowl portion 304, which first conforms to the bulge, and then slowly compresses both the prostate tissue 310 and that non-prostate tissue 308 which intervenes between prostate tissue 310 and bowl portion 304 of

inflated prostate balloon 302, to finally reach the state shown in Figure 3, without any substantial discomfort to the patient.

Microwave power transmitted from two or more separated antennas may be used to simultaneously irradiate the diseased prostate of a patient. Thus, both the urethral and rectal catheters disclosed herein may be used at the same time to treat prostate disease. In fact, some or all of the irradiating microwave power may originate from outside of the patient's body, so long as squeezing pressure is then being applied to the prostate, preferably from the urethra, in accordance with the principles of this invention.

In addition to the advantages of the present invention discussed above, it is believed that the simultaneous application of both squeezing pressure and heat to an enlarged prostate cooperate synergistically to effect a significantly more lasting deformation (i.e., reduction in size) of the enlarged prostate for a prolonged period of time after the heat and pressure have been removed, than could be obtained by the use of either squeezing pressure or heat alone.

What is claimed is:

1 1. In a catheter adapted to be inserted into an
2 orifice of a male patient for treating prostate disease, wherein
3 said catheter comprises means including microwave antenna means
4 for irradiating said patient's prostate with a given distribution
5 of microwave field intensity, thereby to heat tissue of said
6 patient to a temperature which tends to vary as a direct function
7 of microwave power and as an inverse function of the distance of
8 that tissue to said microwave antenna means, and wherein the
9 maximum microwave power to be employed is limited to an amount at
10 which the temperature of the patient's heated tissue most
11 proximate to said microwave antenna means does not exceed a given
12 safe maximum temperature; the improvement wherein said catheter
13 further comprises:

14 an inflatable balloon (1) which is adapted to be in a
15 deflated state while said catheter is being inserted into said
16 orifice, (2) which is located in said catheter at a position
17 which is in cooperative relationship with said patient's prostate
18 when said catheter is fully inserted, and (3) which is adapted to
19 be inflated when said catheter is fully inserted for applying
20 squeezing pressure to both prostate tissue and that non-prostate
21 tissue situated between said inflated balloon and said prostate
22 tissue, thereby increasing the minimum distance between heated
23 tissue of said patient and said microwave antenna means;

24 whereby the maximum microwave power may be increased
25 without exceeding said given maximum safe temperature and the
26 temperature differential between the heated prostate tissue more
27 proximate to said microwave antenna means and the heated prostate
28 tissue more distal to said one microwave antenna means is
29 reduced.

1 2. The catheter defined in Claim 1, wherein said
2 orifice is said patient's urethra, and wherein:

3 said balloon, when inflated, forms a circumferentially
4 symmetrical toroid that extends around the entire circumference

5 of said catheter for applying substantially equal squeezing
6 pressure to the surrounding prostate tissue, thereby effectively
7 increasing the internal diameter of said prostate; and
8 said microwave antenna means is located substantially
9 on the central axis of said catheter for applying a substantially
10 angularly uniform distribution of microwave field intensity to
11 said prostate tissue.

1 3. The catheter defined in Claim 2, wherein:
2 said catheter further comprises a lumen and a second
3 inflatable balloon disposed at the end of said catheter which is
4 in cooperative relationship with the patient's bladder when the
5 catheter is fully inserted, for securing said catheter to said
6 bladder when said second balloon is inflated and permitting urine
7 to be transported through said lumen to the outside of said
8 patient's body.

1 4. The catheter defined in Claim 3, wherein:
2 said catheter further comprises means including a
3 second lumen for circulating a coolant for removing heat
4 generated by said microwave power, whereby the maximum microwave
5 power may be increased to heat the prostate tissue more distal
6 from said microwave antenna means to a higher temperature without
7 concurrently exceeding said given safe maximum temperature for
8 the patient's heated tissue most proximate to said microwave
9 antenna means.

1 5. The catheter defined in Claim 1, wherein said
2 orifice is said patient's rectum, and wherein:
3 said means including said microwave antenna means
4 comprises distribution means for providing a distribution of
5 microwave field intensity that preferentially heats said
6 patient's tissue in a direction towards said patient's prostate
7 more than said patient's tissue in a direction away from said
8 patient's prostate.

1 6. The catheter defined in Claim 5, wherein:
2 said microwave antenna means is offset from the axis of
3 said catheter in a direction adapted to be oriented toward said
4 patient's prostate when said catheter is fully inserted in said
5 patient's rectum.

1 7. The catheter defined in Claim 5, wherein:
2 said microwave antenna means includes a reflector
3 adapted to be oriented to provide said distribution of microwave
4 field intensity when said catheter is fully inserted in said
5 patient's rectum.

1 8. The catheter defined in Claim 5, wherein:
2 said microwave antenna means includes a phased array
3 adapted to provide said distribution of microwave field intensity
4 when said catheter is fully inserted in said patient's rectum.

1 9. The catheter defined in Claim 5, wherein:
2 said balloon, when fully inserted and inflated, is
3 configured to substantially conform to a bulge in the patient's
4 rectum caused by an enlarged prostate.

1 10. The catheter defined in Claim 5, wherein:
2 said catheter further comprises means including a
3 second lumen for circulating a coolant for removing heat
4 generated by said microwave power, whereby the maximum microwave
5 power may be increased to heat the prostate tissue more distal
6 from said microwave antenna means to a higher temperature without
7 concurrently exceeding said given safe maximum temperature for
8 the patient's heated tissue most proximate to said microwave
9 antenna means.

1 11. The catheter defined in Claim 1, wherein:
2 said balloon is inflated with a radio-opaque liquid,
3 whereby the position of said balloon with respect to said

4 patient's prostate can be monitored when said catheter is
5 inserted in said patient's orifice.

1 12. A method for treating prostate disease of a
2 patient, said method comprising the steps of:
3 applying squeezing pressure to non-prostate tissue
4 which surrounds an orifice of the patient in the vicinity of the
5 patient's prostate thereby to compress the prostate; and
6 while said pressure is being applied, irradiating said
7 prostate with microwave power sufficient to heat that prostate
8 tissue which is more distal to said orifice to a first therapeutic
9 temperature without heating any non-prostate tissue of the
10 patient above a maximum safe temperature.

1 13. The method defined in Claim 12, wherein:
2 the step of applying squeezing pressure comprises
3 applying squeezing pressure to that non-prostate tissue which
4 surrounds the patient's urethra thereby to increase the diameter
5 of said urethra; and
6 the step of irradiating said prostate includes the step
7 of irradiating said prostate from said urethra.

1 14. The method defined in Claim 13, further comprising
2 the step of:
3 while said pressure is being applied to said tissue
4 surrounding said patient's urethra and said prostate is being
5 irradiated with microwave power from said patient's urethra,
6 irradiating said patient's prostate from a position outside of
7 said patient's urethra through second non-prostate tissue that is
8 situated between said outside position and said prostate tissue
9 with additional microwave power, said additional microwave power
10 being sufficient to heat that prostate tissue which is more
11 distal to said urethra and is situated between said patient's
12 urethra and said second non-prostate tissue to a second therapeutic
13 temperature that is higher than said first therapeutic

14 temperature without heating said second non-prostate tissue above
15 a maximum safe temperature.

1 15. The method defined in Claim 13, further comprising
2 the steps of:

3 while said pressure is being applied to said tissue
4 surrounding said patient's urethra, applying additional squeezing
5 pressure to tissue of the patient's rectum in the vicinity of the
6 patient's prostate; and

7 while said prostate is being irradiated with microwave
8 power from said patient's urethra, irradiating said patient's
9 prostate from said patient's rectum with additional microwave
10 power sufficient to heat that prostate tissue which is more
11 distal to said urethra and is situated between said patient's
12 urethra and rectum to a second therapeutic temperature that is
13 higher than said first therapeutic temperature without heating
14 non-prostate tissue proximate to said patient's rectum above a
15 maximum safe temperature.

FIG. 1 ✓

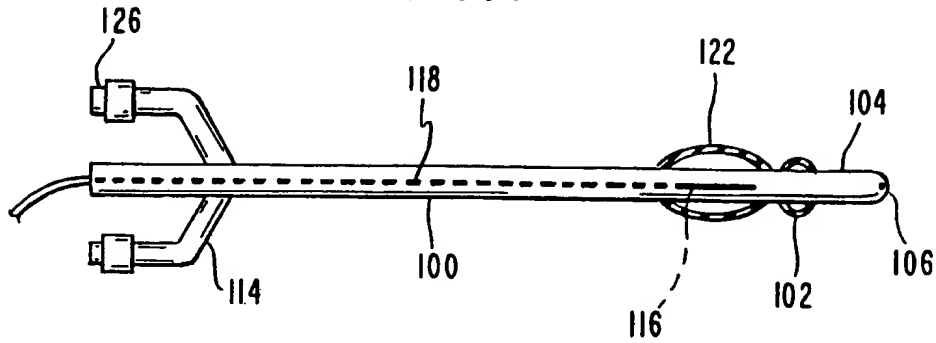


FIG. 1b

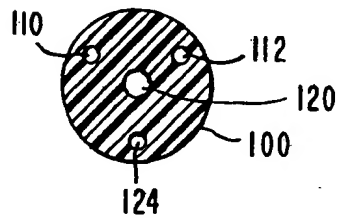


FIG. 1a



FIG. 1c

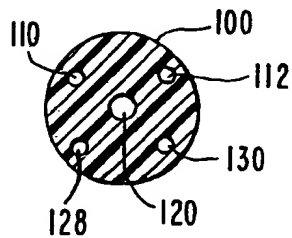
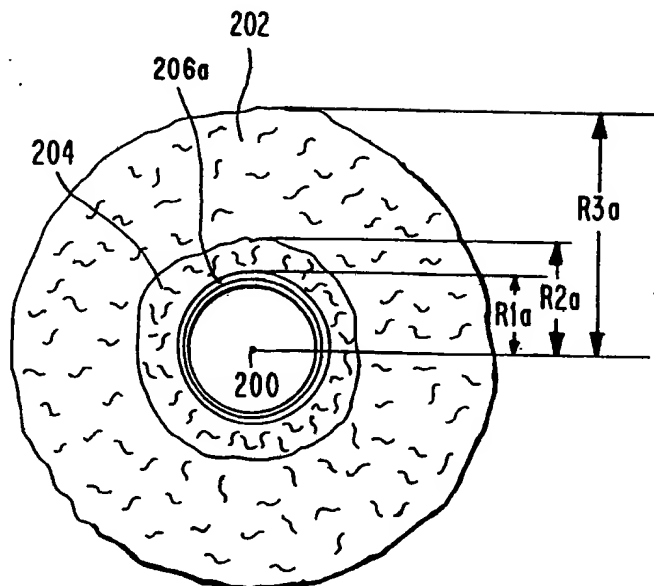
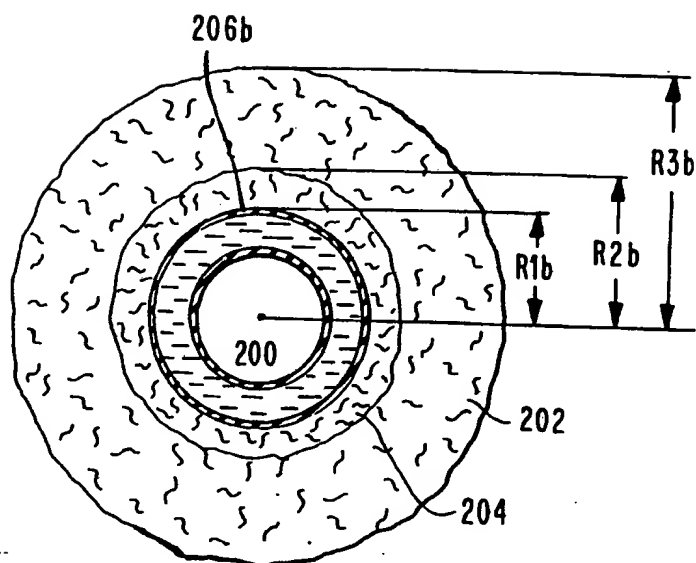
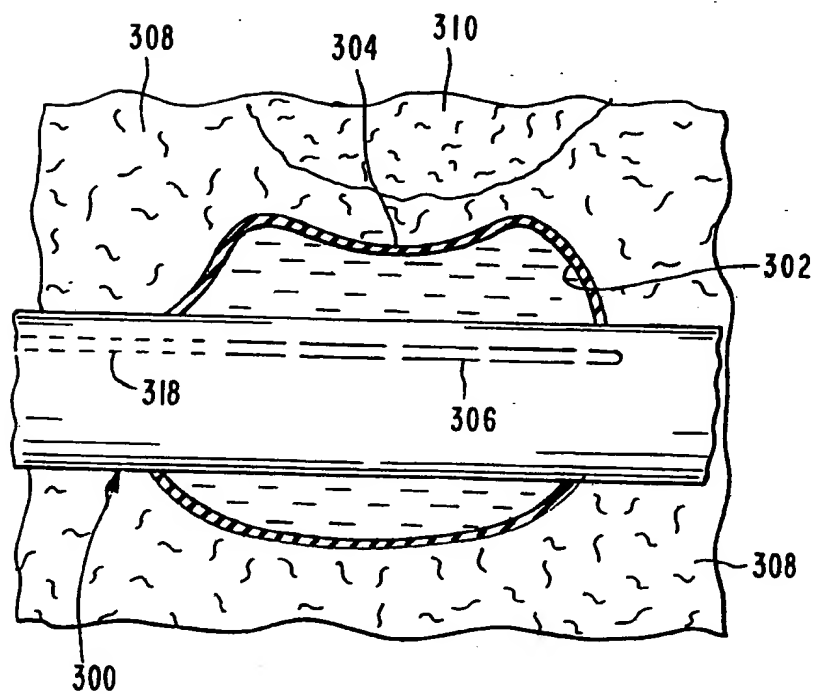


FIG. 2a



**FIG. 2b****FIG. 3**

3/4

FIG. 3a

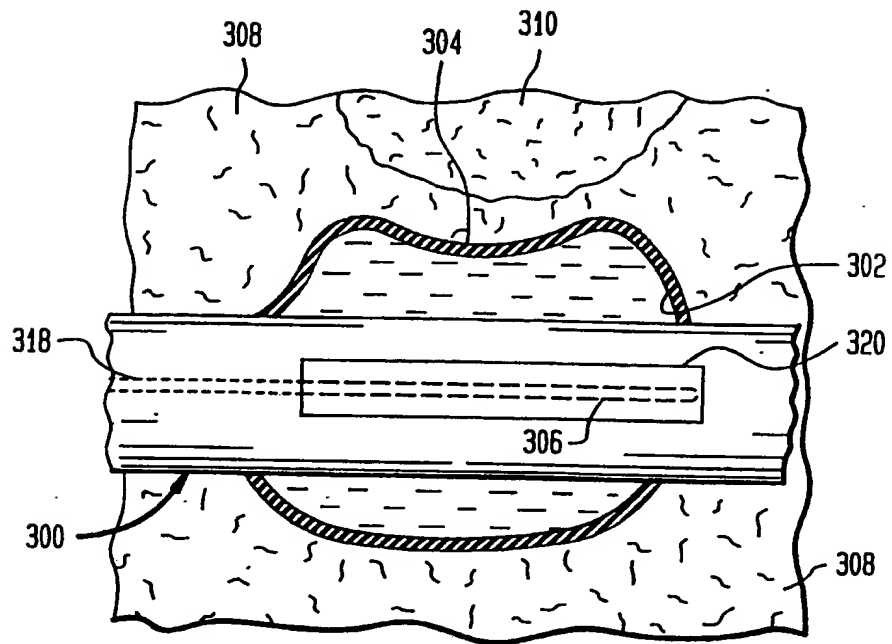
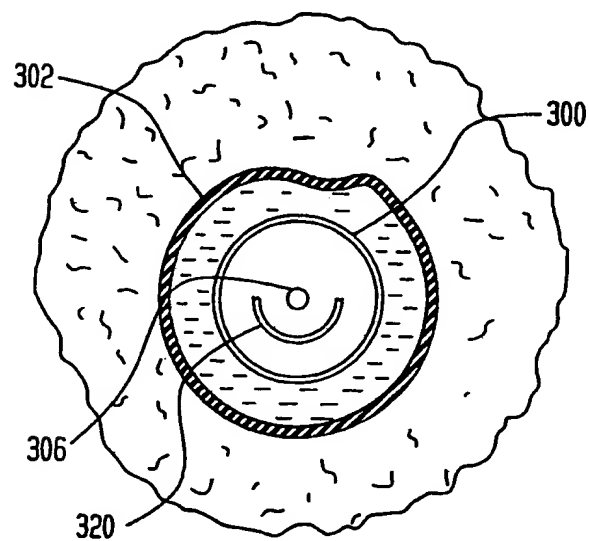


FIG. 3b



SUBSTITUTE SHEET

FIG. 3c

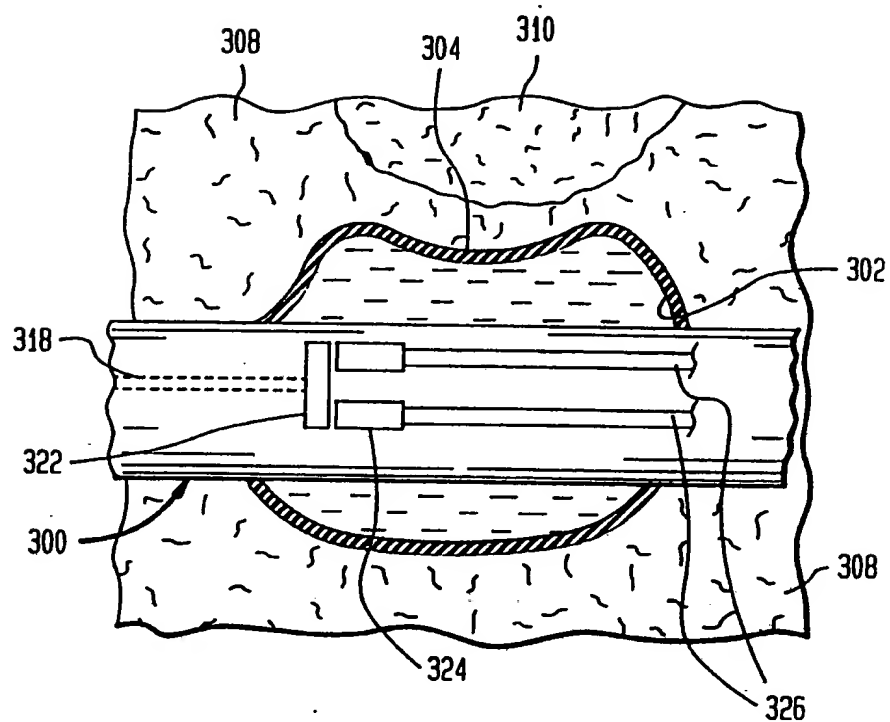
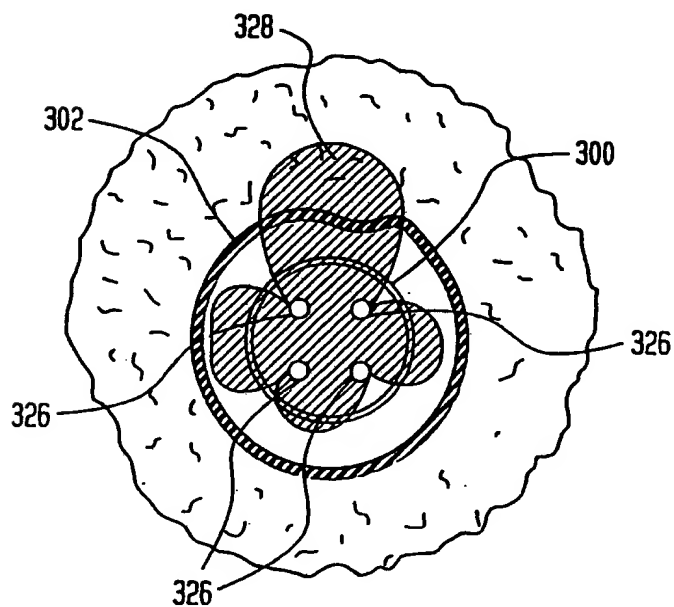
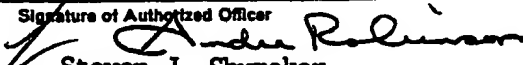


FIG. 3d



INTERNATIONAL SEARCH REPORT

International Application No. PCT/US91/02509

I. CLASSIFICATION OF SUBJECT MATTER (If several classification symbols apply, indicate all) *		
According to International Patent Classification (IPC) or to both National Classification and IPC		
IPC (5): A61N 5/02		
U.S. Cl.: 128/786		
II. FIELDS SEARCHED		
Minimum Documentation Searched ⁷		
Classification System	Classification Symbols	
U.S.	606/27, 28, 29, 33, 34, 41, 46 128/783-788, 804	
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched ⁸		
III. DOCUMENTS CONSIDERED TO BE RELEVANT *		
Category ⁹	Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹³
X Y	US, A, 4,823,812 (ESHEL ET AL.) 04 April 1989	1, 5, 7, 10, 11, 12 2
Y	US, A, 4,662,383 (SOGAWA ET AL.) 05 May 1991	1, 2
A, E	US, A, 5,007,437 (STERZER) 16 April 1991	1-15
A	US, A, 4,311,154 (STERZER ET AL.) 19 January 1982	1-15
A	US, A, 4,676,258 (INOKUCHI ET AL.) 30 January 1987	1-15
A	US, A, 4,601,296 (YERUSHAMI) 22 July 1986	1-15
<p>* Special categories of cited documents: ¹⁰</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"&" document member of the same patent family</p>		
IV. CERTIFICATION		
Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report	
20 June 1991	01 AUG 1991	
International Searching Authority	Signature of Authorized Officer	
ISA/US	 Steven J. Shumaker	